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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,011	08/02/2001	Svetlana A. Dambinova	08805.105001	8646

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KING & SPALDING
191 PEACHTREE STREET, N.E.
ATLANTA, GA 30303-1763

EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,011	DAMBINOVA, SVETLANA A.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25 and 34-40, drawn to a method for diagnosing a central nervous system disorder comprising measuring the level of NR2A and/or NR2B NMDA receptor, other than by measuring autoantibodies against a full sequence NR2A and/or NR2B receptor, classified in class 435, subclass 4.

II. Claims 1-3 and 26-40, drawn to a method for diagnosing a central nervous system disorder comprising measuring the level of NR2A and/or NR2B NMDA receptor comprising measuring the levels of NR2A and/or NR2B autoantibody, classified in class 435, subclass 7.1.

III. Claims 41-45, drawn to a method for diagnosing a central nervous system disorder comprising directly or indirectly measuring the level of NR2A or NR2B receptor and the level of one or more agonists or antagonists of the NR2A and/or NR2B receptor in a subject, classified in class 435, subclass 7.1.

IV. Claim 46, drawn to a composition comprising a fragment of a polynucleic acid encoding the NR2A or NR2B subunit, classified in class 536, subclass 23.1.

V. Claims 47 and 50-52, drawn to a composition comprising an oligo- or polynucleotide, classified in class 536, subclass 23.1.

VI. Claim 48, drawn to a protein fragment comprising the N-terminal domain of the NR2A or NR2B NMDA receptor, classified in class 530, subclass 300.

VII. Claim 49, drawn to a peptide or polypeptide, classified in class 530, subclass 350.

VIII. Claims 53-56 and 60-62, drawn to a kit comprising poly- or monoclonal antibodies to NR2A and/or NR2B proteins immobilized on a carrier, classified in class 530, subclass 387.1.

IX. Claims 57, drawn to a kit comprising protein fragments comprising the N-terminal domain of a NR2A and/or NR2B NMDA receptor, poly-monoclonal antibodies, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to

different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups IV-IX are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the polynucleic acid *fragment* of Group IV, which is structurally and functionally different from the other products, encodes the N-terminal domain of the NR2A or NR2B NMDA receptor and can be used other than to make the protein of Group VI, such in gene therapy or as a probe in nucleic acid hybridization assays. The DNA of Group V, which is structurally and functionally different from the other products, is a polynucleotide comprising a specific SEQ ID NO and can be used other than to make the protein of Group VII, such in gene therapy or as a probe in nucleic acid hybridization assays. The test kit of Group VIII comprises poly- or monoclonal antibodies to NR2A and/or NR2B proteins, which are structurally different from the products of Groups V-VII and IX can be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The test kit of Group IX comprises protein fragments of the N-terminal domain of a NR2A and/or NR2B NMDA receptor, poly- or monoclonal antibodies immobilized on a carrier, and an indicator reagent comprising a secondary antibody, which are structurally and functionally different from the products of Groups IV-VIII.

b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions I-III are different methods because they require different ingredients, process steps, and endpoints. Groups I-III are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of measuring the level of NR2A and/or NR2B NMDA receptor in a sample other than by measuring autoantibodies against a full

sequence of NR2A and/or NR2B receptor, which is not required by the other inventions. Invention II requires search and consideration of measuring the level of NR2A and/or NR2B NMDA receptor in a sample by measuring autoantibodies against NR2A and/or NR2B receptor, which is not required by the other inventions. Invention III requires search and consideration of diagnosing a central nervous system disorder comprising measuring the level of NR2A or NR2B NMDA receptor and the level of one or more agonists or antagonists, which is not required by the other inventions.

c. Inventions IV/V/VI/VII and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products claimed can be used in materially different methods, such as gene therapy or for the production of antibodies.

d. Inventions VI and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different methods, such as therapeutic methods or for the production of antibodies.

e. Inventions IV-IX and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case, the products claimed can be used in materially different methods, such as gene therapy or for the production of antibodies.

f. Inventions VIII/IX and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups VIII/IX and I are unrelated products and method, wherein each is not required, one for another. For example, the claimed method of Inventions I does not recite the use or production of the protein fragments and antibodies of Inventions VIII/IX.

g. Inventions IV/V/VII/VIII/IX and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups IV/V/VII/VIII/IX and II are unrelated products and method, wherein each is not required, one for another. For example, the claimed method of Invention II does not recite the use or production of the polynucleotides, proteins, and antibodies of Inventions IV/V/VII/VIII/IX.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, separate search requirements, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Groups A-F. The inventions as they pertain to each of amino acid SEQ ID NOs: 2, 3, 4, 11, 12, 13, classification dependent upon the nature of the inventions.

The inventions are distinct, each from the other because of the following reasons:

h. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs: 2, 3, 4, 11, 12, and 13 is a unique amino acid sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements and divergent subject matter, restriction for examination purposes as indicated is proper.

3. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Groups G-L. The inventions as they pertain to each of the nucleotide sequences of SEQ ID NOs: 6, 7, 8, 9, 15, 15, 17, classification dependent upon the nature of the inventions.

The inventions are distinct, each from the other because of the following reasons:

i. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs: 6, 7, 8, 9, 15, 15, 17 is a unique nucleotide sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements and divergent subject matter, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for diagnosing a central nervous system disorder comprising measuring the level of NR2A and/or NR2B NMDA receptor, wherein the NMDA receptor is:

a. NR2A

b. NR2B

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for diagnosing a central nervous system disorder comprising measuring the level of NR2A and/or NR2B NMDA receptor, wherein the NMDA receptor is measured :

c. directly from the level of the N-terminal domain of a NR2A and/or NR2B NMDA receptor

d. indirectly from the level of antibodies against the N-terminal domain of a NR2A and/or NR2B NMDA receptor

e. indirectly from the mRNA encoding the NR2A and/or NR2B NMDA receptor

f. directly from the level of the peptide

g. indirectly from the level of antibodies against a peptide

h. directly from the level of cDNA

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 4-9 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for diagnosing a central nervous system disorder comprising measuring the level of NR2A and/or NR2B NMDA receptor, wherein if TIA and/or stroke is confirmed:

i. administering ischemic or hemorrhagic stroke therapy

j. administering TIA or stroke therapy

k. administering therapy consistent with the extent of the cranial infarct

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 12-14 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In order to be fully responsive, Applicant must select one invention from Groups I-IX, one amino acid sequence from Groups A-F, and nucleotide sequence from Groups G-L. Applicant is advised that neither I-IX, A-F, and G-L are species election requirements; rather, each of I-IX, A-F, and G-L is a restriction requirement.

If Applicant selects Inventions I-IX, one species from the NMDA receptor group must also be chosen to considered fully responsive.

If Applicant selects Inventions I-II, one species from the NDMA receptor group, one species from the NMDA measurement group, and species for the therapy group must also be chosen to be considered fully responsive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Elyabeth C. Kemmerer

BEB
Art Unit 1647
December 16, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER